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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,065	07/09/2004	Patrick Chesne	REGIM 3.3-025	1671
530 7590 10/15/2008 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090				
EXAMINER CROUCH, DEBORAH				
ART UNIT		PAPER NUMBER		
1632				
MAIL DATE		DELIVERY MODE		
10/15/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/501,065

**Applicant(s)**

CHESNE ET AL.

**Examiner**

Deborah Crouch, Ph.D.

**Art Unit**

1632

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-20, 25-33, 38-45 and 51-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-20, 25-33, 38-45 and 51-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/21/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 28, 2008 has been entered.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-20, 25-33, 38-43, 45 and 51-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1, 26 and 39 require the determination of asynchrony of development between two embryos of the same nonprimate mammalian species, where  $T =$  Asynchrony of Development. However, the claims are not enabled because there is insufficient guidance for performing the calculation and using the result.

In the claims, exemplified by claim 1, steps (a)(i) and (a)(ii) provide for a first and second embryo. In step (a)(i), a vasectomized male is mated with a female to produce the first embryo. However, such a mating would not produce an embryo as a

vasectomized male does not produce sperm. Without sperm there would be no fertilization of the female's egg(s), the eggs would disintegrate and thus no embryos. This technique produces a pseudo-pregnant female that would be receptive to the implantation of a fertilized egg or embryo, but the method does not produce embryos. The specification does not offer any clarity on this issue as it also discloses mating a vasectomized male mouse with a female mouse and isolating embryos. It is noted that the specification states "preferably vasectomized" (specification, page 2, lines 36-38). While the issue of vasectomized males producing embryos remains, applicant may consider amending the claim to eliminate vasectomized unless evidence is presented to contradict the inability of vasectomized males to produce embryos.

In step (ii) determination takes place prior to introduction of the embryo of step a(ii.). The claims are not enabled because there is no indication within the claim what has been determined. That is the claim does not state the assay endpoint to determine asynchrony. The claims state, or depend on claims that state, "determining asynchrony" and provide a 2-step method to do so, but the claim does not provide for a characteristic, feature or structure to indicate asynchrony. It appears from the specification, that asynchrony is a developmental stage difference in hours, but the claim provides step (i) and (ii). The two embryos are compared but for what indicator and what result indicates asynchrony? The claim should indicate an endpoint, such as "determining hour differences in developmental stages between the embryos of a(i) and a(ii)".

The specification makes apparent that live rabbits are obtained by nuclear transfer when the NT embryo is transferred to a female rabbit mated 16 or 22 hours after crossing female rabbits to obtain oocytes (specification, page 25, lines 26-39). This shows the production of rabbits when the NT embryo and the surrogate mother rabbit are asynchronous for developmental stage. These same differences in developmental stages between the embryo and the recipient rabbit could also be employed for producing rabbits by embryo transfer regardless of how the embryos are produced.

Thus because an embryo is not produced in claims, 1, 26 and 39, step (a)(i), there cannot be any determination of asynchrony between two embryos as claimed.

Therefore at the time of the present invention, the skilled artisan would have needed to perform an undue amount of experimentation without a predictable degree of success to implement the invention as claimed.

Applicant argues the specification teaches asynchrony of development is the number of hours it takes the first embryo to reach the same stage of development as the second embryo reaches on or before the day the second embryo implants in the uterus. This argument is not persuasive.

Claims 1, 26 and 39 do not require transfer of either embryo produced by steps a(i) and a(ii) or the analysis of embryo implantation stage as compared to an in vitro developed embryo. The parenthetically stated determination of uterine implantation needs to be an active part of the step.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 26 are confusing as step (a)(ii) states the second embryo is to be implanted, but step (b) states the cultured, or manipulated, or cultured and manipulated in vitro embryo is to be transferred. This would be the embryo of step (a)(i). Is the second embryo transferred to the female of step (a)(1)?

Claims 1, 26 are confusing as to "a uterus." should be "the uterus (b, lines 2-3.

Claim 2 is confusing as to the location of the "first embryo." Is the first embryo cultured in vitro up to implantation of the transferred embryo? The confusion resides in "day or implantation" of which embryo.

Claim 25, 38, 39 are confusing as to the "in vitro method." Nuclear transfer to produce a nonprimate mammal is in vitro and in vivo. The method is in vitro for production of the cloned embryo, but in vivo for production of the cloned mammal. There cannot be a in vitro method of nuclear transfer to produce a mammal as the method requires a surrogate mother for term or fetal development. Also the claim should be written as "an in vitro method for cloning a nonprimate mammal" in keeping with the requirement to transfer a nonprimate mammalian embryo.

Claim 39 is confusing as to the reference to claim 26. It isn't clear if claim 39 depends from claim 26, and is meant to further limit.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 43, 44 and 56 rejected under 35 U.S.C. 102(e) as being clearly anticipated by 20040040050 (West).

West teaches the production of non-primate mammals, including rabbits, by nuclear transfer, where a donor cell or donor cell nucleus is inserted into an enucleated oocyte to make a reconstituted or NT embryo (parags. [0006] [0074, [0075], [0090], and [0147]). The NT embryo is activated by incubation in DMAP and cycloheximide ([0133]). Thus, West anticipates the claimed invention.

Claims 1-5, 7-20, 25-33, 38-42 and 45-55 because the prior art did not teach or suggest the methods for producing nonprimate mammals by asynchronous embryo transfer using the particular method for determining asynchrony claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (571)272-0727. The examiner can normally be reached on M-Fri, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch, Ph.D. /  
Primary Examiner, Art Unit 1632

October 15, 2008